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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,545	12/12/2003	Nadji Sourena	01252/1200687-US1	9701
7278	7590	08/15/2006	EXAMINER	
DARBY & DARBY P.C. P. O. BOX 5257 NEW YORK, NY 10150-5257			COLEMAN, BRENDA LIBBY	
			ART UNIT	PAPER NUMBER
			1624	
DATE MAILED: 08/15/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/734,545

Applicant(s)

SOURENA ET AL.

Examiner

Brenda L. Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-21 are pending in the application.

This action is in response to applicant's amendment filed May 30, 2006. Claims 1, 10, 18 and 19 have been amended.

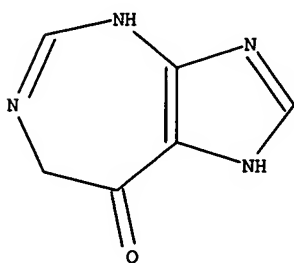
Response to Amendment

Applicant's arguments filed May 30, 2006 have been fully considered with the following effect:

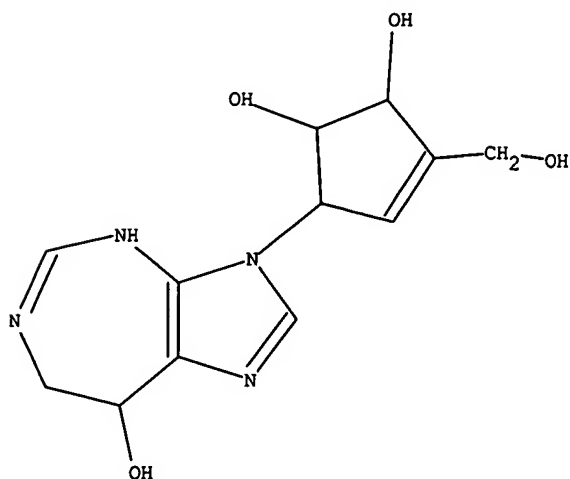
1. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, first paragraph rejection of claim 14, labeled paragraph 1 in the last office action, which is hereby **withdrawn**.
2. The applicant's amendments and arguments are sufficient to overcome the 35 USC § 112, second paragraph rejection labeled paragraph 3b), c), d) and h) of the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled a), e), f) and g) the applicant's amendments and remarks have been fully considered but they are not persuasive.
 - a) The applicants stated that the terms "pentostatin analog", "aglycone", "aglycone analog" are clear to a person of ordinary skill in the art when read with the specification as filed. The specification at page 20 sets forth the following definitions: "pentostatin aglycone" refers to the 5:7 ring system nucleobase of pentostatin; "pentostatin analogs" includes pentostatin molecules with a modified sugar moiety, including the sugar modifications set forth herein (The person of ordinary skill will also understand that pentostatin analogs include substitutions

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along the seven member aglycone ring. The 7-member ring constituents themselves can also be replaced with different constituents. In particular the carbon atom between the two Nitrogen constituents on the seven member ring can be altered based on the orthoester used in cyclization procedure. Further the chirality of the O attached to the seven member aglycone ring can produce stereoisomers, depending on the chirality of the diethyl tartarate starting material.); "pentostatin aglycone analog" includes the 5:7 ring system nucleobase of pentostatin with substitutions along the seven member aglycone ring (The 7-member ring constituents themselves can also be replaced with different constituents. In particular the carbon atom between the two Nitrogen constituents on the seven member ring can be altered based on the orthoester used in cyclization procedure. Further the chirality of the O attached to the seven member aglycone ring can produce stereoisomers, depending on the chirality of the diethyl tartarate starting material.) Based on the definition of pentostatin aglycone the following compound would be a pentostatin aglycone:



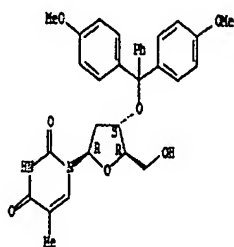
and based on the definition of pentostatin analog the following compound would be a pentostatin analog



of which are neither supported or contemplated. The applicant's specification does not sufficiently define the applicants' metes and bounds of the compounds as claimed herein.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

e) The applicants stated that the term "DMT derivative" are clear to a person of ordinary skill in the art when read with the specification as filed and that DMT (aka Dimethoxytrityl) compounds have a dimethoxy trityl group and a fourth group such as chlorine to form, for example DMT-chloride or an -OR group to form a DMT-ether. Based on the applicants' definition of DMT derivative in their remarks the following compound would be a DMT derivative:

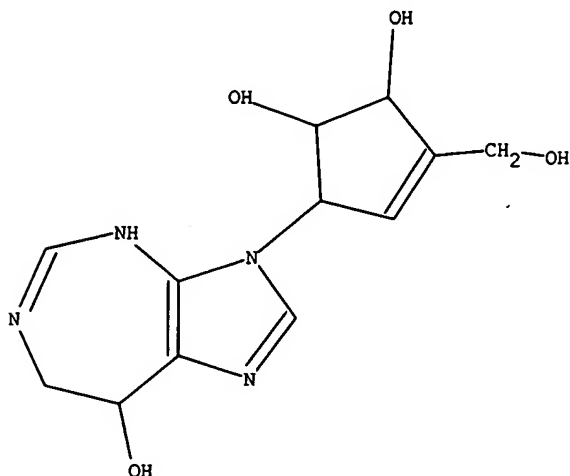


of which is neither supported or contemplated. The applicant's specification does not sufficiently define the applicants' metes and bounds of the compounds as claimed herein.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

f) The applicants stated that the term "pentostatin analog" is clear to a person of ordinary skill in the art when read with the specification as filed. The specification at page 20 sets forth the following definitions: "pentostatin analogs" includes pentostatin molecules with a modified sugar moiety, including the sugar modifications set forth herein (The person of ordinary skill will also understand that pentostatin analogs include substitutions along the seven member aglycone ring. The 7-member ring constituents themselves can also be replaced with different constituents. In particular the carbon atom between the two Nitrogen constituents on the seven member ring can be altered based on the orthoester used in cyclization procedure. Further the chirality of the O attached to the seven member aglycone ring can produce stereoisomers, depending on the chirality of

the diethyl tartarate starting material.) Based on the definition of pentostatin analog the following compound would be a pentostatin analog



of which is neither supported or contemplated. The applicant's specification does not sufficiently define the applicants' metes and bounds of the compounds as claimed herein.

Claims 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

g) The applicants stated that "to form a substituted imidazole compound" should have been recited in claim 18 instead of claim 19. However, the rejection as set forth in paragraph 2g) is such that it is not known what is meant by substituted imidazole, i.e. it is not known what is substituted on the imidazole.

Claims 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicant regards as the invention, for reasons of record and stated above.

In view of the amendment dated May 30, 2006, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claims 5-10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claims 5, 7, 8, 10 and claims dependent thereon are vague and indefinite in that it is not known what is meant by amine. It is not known which amine this is referring to.
- b) Claim 15 is vague and indefinite in that it is not further limiting of claim 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Brenda L. Coleman
Primary Examiner Art Unit 1624
August 14, 2006